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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,308	01/10/2001	Howard A. Fields	14114.0349U2	9952

23859 7590 06/30/2004

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,308	FIELDS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-25,and 32-42* is/are pending in the application.

4a) Of the above claim(s) *1,2,4-6,11-16,18-23 and 32-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,9,10,17,24,25 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 22, filed on 02/09/04. Claims 9, 14, 17, 24, have been amended. Claims 7-8, 26-31 nave been canceled. New claims 41-42 are added. It is noticed that the newly submitted amended does not contain claim 23. Because applicants have not officially cancel the claim 23, claim 23 is still treated as a pending claim. Claims 1-6, 9-25, 32-42 are pending.

The rejection of claim 14 anticipated by Yagi et al. and rejection of claims 14-15 by Barrera et al are typographic errors. The corrected rejections should apply for claim 4 by Yagi and claims 9-10 by Barrera et al. However, both rejections are moot in turn of the amendment of claims 9 and 10. The examiner apologies for the confusion caused by this mistake.

Claims 1-2, 4-6, 11-6, 18-23, 32-39 are withdrawn from the consideration. Claims 3, 9-10, 17, 24, 25 and 40-42 are considered before the examiner.

Applicants are reminded that in the Office Action the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance is governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Matter

1. Claims 9-10 and 40 are still objected and rejected to under 35 U.S.C. 132.

2. Applicants traverse the rejection and submit that there is nothing ambiquitous or uncertain about the negative limitation. Applicants further use several case laws to argue that there is requirement in the patent law that the specification must state that something can be excluded in order for there to be support for that exclusion because the specification positively recites and discloses HCV polyprotein in many places in the specification (page 2, line 30 to page 3, line 6, recite "HCV polyprotein" repeatedly; see also claims 2.6 as filed, which all recited "HCV polyprotein).

3. Applicants' argument has been respectfully considered; however, it is not found persuasive. Because first, the Office does not allege that the claims with the negative limitation are ambiguous or unclear. Secondly, the examiner agreed with concept of the case laws. However, the rejection is a new matter rejection in that the specification does not have any support for the added negative limitation. The specification has to provide a clear explanation about what the content of "the mosaic polypeptide is not a HCV polypeptide" means or at least the person with skill in the art under stand what the concept of "the mosaic polypeptide is not a HCV polypeptide" is referred to.

4. In general, the recombinant HCV polypeptide can be constructed by optionally linking several epitopes from different antigenic proteins of HCV together and expressed as a recombinant HCV antigen. However it may be called a chimeric HCV protein or recombinant HCV antigen. For example, Chien et al. teach a recombinant chimeric C25 polypeptide of HCV, which is encoded by the combined HCV genetic codes and still exhibit the immunogenicity of HCV protein antigen (Chien et al. Proc. Natl. Acad. Sci. USA, 1992, Vol. 89, pp. 1001-10015, see entire document, especially, Fig. 1 on page 10012).

5. In the instant case, the mosaic polypeptide disclosed by the specification of current application is also a chimeric HCV polypeptide that contains antigenic epitopes from the core protein, NS3 protein, and NS4 protein, and optionally contains an additional antigenic epitopes from either the NS4 protein or the NS5a protein or both (See lines 1-7 on page 5 of specification). The specification also teaches that "the antigenic epitopes and mosaic polypeptides are useful for the generation of antibodies, both monoclonal and polyclonal

antibodies that are reactive with and can be used to detect HCV proteins or peptides in a sample (See lines 5-8 on page 26 of specification). In this context, the mosaic polypeptide is till encoded by the HCV genetic codes and exhibit the HCV immunogenicity. While the mosaic HCV polypeptide may not occur as a whole HCV polyprotein in nature, but it is still a part of HCV polyprotein that exhibits the biological immunogenicity of the HCV polyprotein. Office does not understand by what concept that Applicants define that the mosaic HCV polypeptide is not a kind of HCV polyprotein.

6. MPEP 2173.05 (a) recites: Consistent with the well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer, a patentee or applicant may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings if the written description clearly redefines the terms. See, e.g., Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) ("While we have held many times that a patentee can act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning," in such a situation the written description must clearly redefine a claim term "so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term.");Hormone Research Foundation Inc. v. Genentech Inc., 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990).

7. MPEP 2170.5(h) also recites: Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

8. Considering that nowhere does the specification teach that the content of negative limitation of "mosaic HCV polypeptide is not a HCV polyprotein", the rejection is still therefore maintained.

Conclusion

Claims 3, 24, 25, 41-42 are not in condition for allowance because they depends on the rejected claims. NO claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
Art Unit 1648
June 15, 2004.

James C. Housel 6/28/04

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